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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,891	12/20/2001	Mark B. Roller	MIT-264	3207

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EXAMINER

DAVIS, DANIEL J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/20/2004

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,891

Applicant(s)

ROLLER ET AL.

Examiner

D. Jacob Davis

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4 and 5.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

SPECIES

A single coating is to be elected:

Polylactic acid
Polyglycolic acid
Polycaprolactone
Monoglyderide polyesters
90/10 Polycaprolactone/polyglycolide copolymer
An inorganic coating

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 5 and 9 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

Art Unit: 3731

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Richard Skula on May 13, 2004 a provisional election was made without traverse to prosecute the invention of polycaprolactone/polyglycolide copolymer, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claim 14 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-7, 9-12 and 14 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,093,201 to Cooper et al. in view of applicants' admitted prior art and in further view of WO 93/15682 to Small et al.

Cooper discloses first and second bioabsorbable contacting surfaces. The surfaces may be made of polyglycolic acid (col. 1, lines 16-21). The reference fails to disclose a bioabsorbable coating. Applicants admit in the specification on page 2, paragraph 4, "For example it is known to apply a thin layer of a low coefficient of friction coating (ceramic or diamond-like carbon) on one or more contact surfaces. Such a coating reduces friction between the surfaces of a bone fixing device ... " Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat either one or both of the contact surfaces of the Cooper reference, as taught by the admitted prior art, in order to reduce friction (and hence "device drag").

The coating taught in the admitted prior art is not bioabsorbable. Nevertheless, Smart teaches a bioabsorbable screw having a bioabsorbable coating. The coating has a "low coefficient of friction" (page 9, paragraph 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

Art Unit: 3731

substitute the ceramic coating for a bioabsorbable one so that the entire device can be absorbed into the body. Smart teaches that polyglycolic acid (PGA) is glycolide, and that PGA may be used as a low friction coating (page 9, paragraphs 2 and 3).

Claims 4, 8 and 13 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,093,201 to Cooper et al., in view of applicants' admitted prior art, in view of WO 93/15682 to Small et al., in view of EP 0 441 537 to Bezwada et al., and in further of U.S. Patent No. 4,547,542 to Lundberg et al. Small teaches a copolymer of 85 epsilon-caprolactone and 15 glycolide.

Bezwada teaches that instead of 85 percent, the preferred mole ratio for epsilon-caprolactone is 90 percent (page 2, lines 53-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the epsilon-caprolactone mole ratio from 85 percent to 90 percent, as taught by Bezwada.

Lundberg teaches that epsilon caprolactone may be modified to polycaprolactone to make it more adhesive (Abstract and col.5, lines 50-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the epsilon-caprolactone coating, as taught by Lundberg, to create polycaprolactone enabling the coating to more effectively adhere to the surface of the Cooper device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached at (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD
May 13, 2004


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
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